Complete Summary

GUIDELINE TITLE

Dyspepsia: managing dyspepsia in adults in primary care.

BIBLIOGRAPHIC SOURCE(S)

North of England Dyspepsia Guideline Development Group. Dyspepsia: managing dyspepsia in adults in primary care. Newcastle upon Tyne (UK): Centre for Health Services Research, University of Newcastle; 2004 Aug. 228 p. [466 references]

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

On September 30, 2004, Vioxx (rofecoxib) was withdrawn from the U.S. and worldwide market due to safety concerns of an increased risk of cardiovascular events. See the U.S. Food and Drug Administration (FDA) Web site for more information.

Subsequently, on December 23, 2004, the FDA issued a public health advisory concerning the use of non-steroidal anti-inflammatory drug products (NSAIDs) including the COX-2 selective agents Celebrex (celecoxib), Bextra (valdecoxib), and a non-selective NSAID, naproxen (sold as Aleve, Naprosyn, and other trade name and generic products). See the FDA Web site for more information.

Most recently, on June 15, 2005, the FDA requested that sponsors of all non-steroidal anti-inflammatory drugs (NSAID) make labeling changes to their products. FDA recommended proposed labeling for both the prescription and over-the-counter (OTC) NSAIDs and a medication guide for the entire class of prescription products. All sponsors of marketed prescription NSAIDs, including Celebrex (celecoxib), a COX-2 selective NSAID, have been asked to revise the labeling (package insert) for their products to include a boxed warning, highlighting the potential for increased risk of cardiovascular (CV) events and the well described, serious, potential life-threatening gastrointestinal (GI) bleeding associated with their use. FDA regulation 21CFR 208 requires a Medication Guide to be provided with each prescription that is dispensed for products that FDA determines pose a serious and significant public health concern. See the FDA Web siteFDA Web site for more information.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Dyspepsia

GUIDELINE CATEGORY

Management
Treatment

CLINICAL SPECIALTY

Family Practice
Gastroenterology
Internal Medicine
Pharmacology

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Nurses
Patients
Pharmacists
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To provide evidence-based recommendations to guide healthcare professionals, patients, and carers in the appropriate primary care management of dyspepsia
- To promote the dialogue between professionals and patients on the relative benefits, risks, harms, and costs of treatments

- To identify effective and cost effective approaches to managing the care of adult patients with dyspepsia including diagnosis, referral, and pharmacological and nonpharmacological interventions

TARGET POPULATION

Patients with dyspepsia seen in primary care settings

Note: This guideline does not include patients with dyspepsia during pregnancy or in the hospital setting.

INTERVENTIONS AND PRACTICES CONSIDERED

Referral Guidance for Endoscopy

1. Refer for immediate endoscopic investigation as appropriate
2. Review medications for possible causes of dyspepsia, and stop non-steroidal anti-inflammatory drug (NSAID) use, if applicable
3. Consider differential diagnosis, including cardiac or biliary disease
4. Provide care for uninvestigated dyspepsia if referral for endoscopy is not required

Common Elements of Care

1. Self-treatment including antacids and/or alginate therapy for immediate symptom relief
2. Additional therapy for persistent symptoms affecting patient's quality of life
3. Lifestyle modification (e.g., healthy eating, weight reduction, smoking cessation)
4. Patient education
5. Psychological therapies such as cognitive behavioural therapy and psychotherapy
6. Stepwise reduction of prescription medication in patients requiring long-term management

Uninvestigated Dyspepsia

1. Proton pump inhibitor (PPI)
2. Testing for Helicobacter pylori with breath test or stool antigen test
3. H_2 receptor antagonist (H_2RA) or prokinetic therapy

Reviewing Patient Care

1. Annual review of condition
2. Return to self-treatment
3. Lifestyle modification
4. Routine endoscopic investigation, when appropriate

Treatment for Gastro-oesophageal Reflux Disease

1. Offer full-dose PPI for 1 to 2 months

2. If symptoms recur, offer PPI at lowest dose possible with limited number of repeat prescriptions
3. Discuss treatment on an as-required basis
4. Offer H_2RA or prokinetic therapy if inadequate response to a PPI
5. Consider long-term full-dose PPI therapy for patients who have had dilatation of an oesophageal stricture

Treatment for Peptic Ulcer Disease

1. Offer H. pylori eradication therapy
2. Stop use of NSAIDs if possible
3. Repeat endoscopy for patients with gastric ulcer and H. pylori retesting for H. pylori 6-8 weeks after beginning treatment, depending on the size of the lesion
4. Offer full-dose PPI or H_2RA therapy for 2 months
5. If H. pylori positive, repeat endoscopy and retesting for H. pylori 6 to 8 weeks after treatment
6. Offer full-dose PPI or H_2RA therapy for H. pylori negative patients not taking NSAIDs for 1 to 2 months
7. Discuss harms of continued NSAID use
8. Offer gastric protection or a cyclooxygenase (COX)-2-selective NSAID for patients at high risk and for whom NSAIDs are necessary
9. Rule out alternative diagnosis in patients with unhealed ulcer
10. For recurrent symptoms after initial treatment, offer a PPI at lowest dose with limited number of repeat prescriptions
11. Offer H_2RA therapy

Non-ulcer Dyspepsia

1. Offer eradication therapy for patients positive for H. pylori
2. Routine re-testing after eradication (not recommended)
3. Offer a low-dose PPI or H_2RA for 1 month if H. pylori excluded and symptoms persist
4. Offer a PPI or H2RA at the lowest dose, with a limited number of repeat prescriptions if symptoms continue or recur following initial treatment
5. Long-term, frequent dose, continuous prescription of antacid therapy (not recommended)

H. pylori: Testing and Eradication

Testing

1. Carbon-13 urea breath test
2. Stool antigen test
3. Laboratory-based serology (where performance validated locally)
4. Re-testing using carbon-13 urea breath test
5. Office-based serological tests are not recommended

Treatment

1. For patients testing positive, full-dose PPI with either metronidazole 400 mg and clarithromycin 250 mg or amoxicillin 1 g and clarithromycin 500 mg
2. If a second course is needed, chose a regimen that doesn't include antibiotics given previously.

MAJOR OUTCOMES CONSIDERED

- Effectiveness of symptom evaluation in detecting endoscopically significant disease
- Symptom control
- Quality of life
- Rates of Helicobacter pylori (H. pylori) eradication
- Rates of ulcer healing/cure
- Benefits, risks, harms, and costs of interventions to treat dyspepsia

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The evidence base was derived from published reports, whose review methods are reported comprehensively. Reports were updated with systematic searching for more recent studies when necessary. The expert knowledge and experience of the guideline group was used to augment the evidence base where necessary.

In brief, the published reports were developed using extensive searches of nine databases (MEDLINE, EMBASE, CINAHL, SIGLE, BIDS, AMED PsycLIT, Cochrane Controlled Trial Register, and Cochrane Database of Systematic Reviews) using dyspepsia and therapy-related Medical Subject Heading (MeSH) and text terms. All searches were run from the earliest date available until 2003, and all languages and indexed journals were included. Experts and the pharmaceutical industry were contacted and editors from specialist and general medical journals were asked about work in press.

Retrieved studies were assessed using standard assessment criteria including duplicate publication, randomisation, concealment of allocation, masking, and completeness of data. Authors were contacted where data were missing from published reports.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Evidence Grade

Ia: Evidence from a meta-analysis of randomised controlled trials

Ib: Evidence from at least one randomised controlled trial

IIa: Evidence from at least one controlled study without randomisation

IIb: Evidence from at least one other type of quasi-experimental study

III: Evidence from observational studies

IV: Evidence from expert committee reports or experts

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis of Randomized Controlled Trials
Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Once individual papers had been checked for methodological rigour and clinical significance, the information was synthesised. Trials often have an insufficient sample size to identify significant outcomes with confidence, so where appropriate, the results of randomised studies were combined using meta-analytic techniques. Papers were categorised according to study design, reflecting susceptibility to bias. Questions were answered using the best evidence available. When considering the effect of an intervention, if this could be addressed by the best study design then weaker designs were not reviewed. Where studies were of poor quality, or contained patient groups considered a priori likely to have different responses, the effects of inclusion or exclusion were examined in sensitivity analyses. No trials that met our inclusion criteria were excluded from the primary analyses. However, where data on relevant outcomes included were not available, these studies could not be incorporated, thus leading to the potential for publication bias. A summary of analyses used to describe the results of trials is provided in Appendix 1 of the original guideline document.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Informal Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The guideline development group was run using the principles of small group work and was led by a trained facilitator. The group underwent initial exercises to set its own rules to determine how it wanted to function and received brief training on reviewing methods, economic analysis, and grading methodology. Additional training was provided in the group as the need arose in subsequent meetings. Findings, expressed as narratives, statements of evidence, and recommendations, were reached by informal consensus. There was no obligation to force an agreement where none existing after discussion; if dissensions occurred these are recorded in the guideline narrative.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The grading scheme used in the NICE guideline:

Grade A: Based on hierarchy I evidence

Grade B: Based on hierarchy II evidence or extrapolated from hierarchy I evidence

Grade C: Based on hierarchy III evidence or extrapolated from hierarchy I or II evidence

Grade D: Directly based on hierarchy IV evidence or extrapolated from hierarchy I, II, or III evidence

COST ANALYSIS

Approaches to cost-effectiveness have assisted in reaching recommendations in a series of primary care evidence-based guidelines. This guideline involves a systematic appraisal of effectiveness, compliance, quality-of-life, safety and health service resource use and costs of a medical intervention provided in the British healthcare setting. Using the most current, pertinent, and complete data available, the economic analysis attempts a robust presentation showing the possible bounds of cost-effectiveness that may result.

The guiding principle behind economic analysis is that it is desirable to use limited healthcare resources to maximise health improvements in the population. Well defined but narrow notions of health improvement may not reflect all aspects of value to patients, carers, clinicians, or society. For example, evidence may lead the guideline group to recommend targeting additional resources to certain patient groups when unequal access to care is apparent. The group process allows discussion of what should be included in the definition of "improved health" and, more broadly, of other concepts of value to society such as fairness, justice, dignity or minimum standards of care.

The range of values used to generate cost-effectiveness estimates reflects the available evidence and the concerns of the guideline development group. Recommendations are graded reflecting the certainty with which the costs and consequences of a medical intervention can be assessed. This practice reflects the desire of group members to have simple, understandable and robust information based on good data.

It is not generally helpful to present an additional systematic review of previous economic analyses that have adopted a variety of differing perspectives, analytic techniques and baseline data. However, the economic literature is reviewed to compare guideline findings with representative published economic analyses and to interpret any differences in findings when these occurred. A commentary is included when the group feels this aided understanding.

Findings

Proton Pump Inhibitor Therapy

Although there are no long term trials in endoscopy-negative reflux disease, guideline developers concluded the most cost-effective approach appeared to be to offer patients intermittent one month full dose or "on demand" proton pump inhibitor (PPI) therapy, rather than continuous therapy.

Helicobacter pylori Eradication Therapy

H. pylori eradication therapy was found to be a cost-effective treatment for H. pylori positive patients with peptic ulcer disease. Guideline developers concluded eradication therapy provides additional time free from dyspepsia at acceptable cost in conservative models and is cost-saving in more optimistic models.

Although 14 day therapy gives an almost 10% higher eradication rate, the absolute benefit of H. pylori therapy is relatively modest in non-ulcer dyspepsia (NUD) and undiagnosed dyspepsia and the longer duration of therapy does not appear cost-effective.

In patients with peptic ulcer, increasing the course to fourteen days duration improves the effectiveness of eradication by nearly 10% but does not appear cost-effective.

H. pylori "Test and Treat" Strategy

A Discrete Event Simulation of the management of dyspepsia in primary care was adapted to compare the cost per life year saved by prompt endoscopy-based management and an H. pylori "test and treat" strategy for patients above different age thresholds. The model suggested that up to age 60 years test and treat was likely to save more life years and be cheaper than endoscopy. Even above age 60 the gain in life years was very marginal, and endoscopy based management was not cost-effective.

H. pylori testing and treatment has not been demonstrated to produce better patient outcomes than endoscopy, although there is considerable variation in study findings. However, studies consistently demonstrate that test-and-treat dramatically reduces the need for endoscopy and provides significant cost savings.

Referral for Endoscopy

Early referral for endoscopy resulted in a borderline reduction in dyspepsia at one year (RD: -5%, 95%CI:-10% to +1%), matching the finding of another study.

The incremental cost effectiveness ratio (ICER) in this trial was 1,728 pounds sterling per patient symptom free at one year, but could be reduced to 164 pounds sterling per patient if the unit cost of endoscopy fell from 250 to 100 pounds sterling. Uncertainty was displayed as a cost-effectiveness acceptability curve, as the ICER was not significant at the 95% level. The maximum certainty that initial endoscopy is cost effective at any value of the ICER is 80%.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The process involved identifying and registering relevant patient and professional organizations as stakeholders; obtaining their comments on the scope of the work; providing an opportunity for the submission of relevant evidence and commenting on two draft versions of the final document. Comments were collated by the Institute and a response was provided by the guideline developers and fed back to stakeholders. An independent panel convened by the Institute to assess the draft versions and comments had responsibility for reviewing the completed guideline and for providing advice to NICE.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Recommendation grades (A-D) are defined at the end of the Major Recommendations field. Note: the reported grading scheme is the one available in the National Institute for Health and Clinical Excellence (NICE) guideline

The Community Pharmacist

D - Offer initial and ongoing help for people suffering from symptoms of dyspepsia. This includes advice about lifestyle changes, using over-the-counter medication, help with prescribed drugs, and advice about when to consult a general practitioner.

D - Pharmacists record adverse reactions to treatment and may participate in primary care medication review clinics.

Referral Guidance for Endoscopy

D - Immediate (same day) specialist referral is indicated for patients presenting with dyspepsia together with significant acute gastrointestinal bleeding.

D - Review medications for possible causes of dyspepsia, for example calcium antagonists, nitrates, theophyllines, bisphosphonates, steroids, and non-steroidal anti-inflammatory drugs [NSAIDs]). In patients requiring referral, suspend NSAID use.

D - Consider the possibility of cardiac or biliary disease as part of the differential diagnosis.

C - Urgent specialist referral or endoscopic investigation (to be seen within 2 weeks) is indicated for patients of any age with dyspepsia when presenting with any of the following: chronic gastrointestinal bleeding, progressive unintentional weight loss, progressive difficulty swallowing, persistent vomiting, iron deficiency anaemia, epigastric mass, or suspicious barium meal.

C - Routine endoscopic investigation of patients of any age, presenting with dyspepsia and without alarm signs, is not necessary. However, for patients over 55, when symptoms persist despite Helicobacter pylori testing and acid suppression therapy, consider endoscopic referral for any of the following: previous gastric ulcer or surgery; continuing need for NSAID treatment; or raised risk of gastric cancer or anxiety about cancer.

D - Patients undergoing endoscopy should be free from medication with either a proton pump inhibitor (PPI) or an H_2 receptor antagonist (H_2RA) for a minimum of 2 weeks beforehand.

D - Consider managing previously investigated patients without new alarm signs according to previous endoscopic findings.

Common Elements of Care

D - For many patients, self treatment with antacid and/or alginate therapy (either prescribed or purchased over-the-counter and taken as required) may continue to be appropriate for immediate symptom relief. However, additional therapy becomes appropriate to manage symptoms which persistently affect patients' quality of life.

D - Offer older patients (over 80 years of age) the same treatment as younger patients, taking account of any comorbidity and their existing use of medication.

C - Offer simple lifestyle advice, including advice on healthy eating, weight reduction, and smoking cessation.

D - Advise patients to avoid known precipitants they attribute to their dyspepsia where possible. These include smoking, alcohol, coffee, chocolate, fatty foods, and being overweight. Raising the head of the bed and having a main meal well before going to bed may help some people.

D - Provide patients with access to educational materials to support the care they receive.

B - Psychological therapies, such as cognitive behavioural therapy and psychotherapy, may reduce dyspeptic symptoms in the short term in individual patients. Given the intensive and relatively costly nature of such interventions, routine provision by primary care teams is not currently recommended.

D - Patients requiring long-term management of symptoms for dyspepsia should be encouraged to reduce their use of prescribed medication stepwise: by using the effective lowest dose, by trying "on-demand" use when appropriate, and by returning to self treatment with antacid and/or alginate therapy.

Interventions for Uninvestigated Dyspepsia

D- Dyspepsia in unselected patients in primary care is defined broadly to include patients with recurrent epigastric pain, heartburn, or acid regurgitation, with or without bloating, nausea, or vomiting.

A - Initial therapeutic strategies for dyspepsia are empirical treatment with a PPI or testing for and treating H. pylori. There is currently insufficient evidence to guide which should be offered first. A 2-week washout period following PPI use is necessary before testing for H. pylori with a breath test or a stool antigen test.

A - Offer empirical full-dose PPI therapy for 1 month to patients with dyspepsia.

A - Offer H. pylori "test and treat" to patients with dyspepsia.

A - If symptoms return after initial care strategies, step down PPI therapy to the lowest dose required to control symptoms. Discuss using the treatment on an as-required basis with patients to manage their own symptoms.

A - Offer H_2RA or prokinetic* therapy if there is an inadequate response to a PPI.

*Cisapride is no longer licensed in the UK and evidence is sparse for domperidone or metoclopramide.

Reviewing Patient Care

D - Offer patients requiring long-term management of dyspepsia symptoms an annual review of their condition, encouraging them to try stepping down or stopping treatment*.

*Unless there is an underlying condition or comedication requiring continuing treatment

D - A return to self treatment with antacid and/or alginate therapy may be appropriate, either prescribed or purchased over-the-counter and taken as-required.

C - Offer simple lifestyle advice, including healthy eating, weight reduction, and smoking cessation.

D - Advise patients to avoid known precipitants they associate with their dyspepsia where possible. These include smoking, alcohol, coffee, chocolate, fatty foods, and being overweight. Raising the head of the bed and having a main meal well before going to bed may help some people.

C - Routine endoscopic investigation of patients of any age, presenting with dyspepsia and without alarm signs is not necessary. However, in patients over 55, consider endoscopy when symptoms persist despite H. pylori testing and acid

suppression therapy and patients have one of more of the following: previous gastric ulcer or surgery, continuing need for NSAID treatment or the risk of gastric cancer or anxiety about cancer.

Interventions for Gastro-oesophageal Reflux Disease

D - Gastro-oesophageal reflux disease (GORD) refers to endoscopically-determined oesophagitis or endoscopy negative reflux disease. Patients with uninvestigated "reflux-like" symptoms should be managed as patients with uninvestigated dyspepsia.

A - Offer patients with GORD a full-dose PPI for 1 or 2 months.

A - If symptoms recur following initial treatment, offer a PPI at the lowest dose possible to control symptoms, with a limited number of repeat prescriptions.

A - Discuss using the treatment on an "on-demand" basis with patients to manage their own symptoms.

A - Offer H_2RA or prokinetic therapy* if there is an inadequate response to a PPI.

*Cisapride is no longer licensed in the UK and evidence is sparse for domperidone or metoclopramide.

A - Surgery cannot be recommended for the routine management of persistent GORD although individual patients whose quality-of-life remains significantly impaired may value this form of treatment.

D - Patients who have had dilatation of an oesophageal stricture should remain on long-term full dose PPI therapy.

Interventions for Peptic Ulcer Disease

A - Offer H. pylori eradication therapy to H. pylori-positive patients who have peptic ulcer disease.

B - For patients using NSAIDs with diagnosed peptic ulcer, stop the use of NSAIDs where possible. Offer full dose PPI for two months to these patients and if H. pylori is present subsequently offer eradication therapy.

D - Patients with gastric ulcer and H. pylori should receive repeat endoscopy, retesting for H. pylori 6 to 8 weeks after beginning treatment, depending on the size of the lesion.

B - Offer full dose PPI therapy to H. pylori negative patients not taking NSAIDs for one or two months.

C - For patients continuing to take NSAIDs after a peptic ulcer has healed, discuss the potential harm from NSAID treatment. Review the need for NSAID use regularly (at least 6 monthly) and offer a trial of use on a limited, "as-required" basis. Consider dose reduction, substitution of an NSAID with paracetamol, use of an alternative analgesic, or low dose ibuprofen (1.2 g daily).

A - In patients at high risk (previous ulceration) and for whom NSAID continuation is necessary, offer gastric protection or consider substitution to a cyclooxygenase (Cox)-2-selective NSAID.

C - In patients with unhealed ulcers, exclude non-adherence, malignancy, failure to detect H. pylori, inadvertent NSAID use, other ulcer-inducing medication, and rare causes such as Zollinger-Ellison syndrome or Crohn's disease.

B - If symptoms recur following initial treatment, offer a PPI to be taken at the lowest dose possible to control symptoms, with a limited number of repeat prescriptions. Discuss using the treatment on an "on-demand" basis with patients to manage their own symptoms.

B - Offer H_2RA therapy if there is an inadequate response to a PPI.

Interventions for Non-ulcer Dyspepsia

A - Management of endoscopically-determined non-ulcer dyspepsia involves initial treatment for H. pylori if present, followed by symptomatic management and periodic monitoring.

A - Patients testing positive for H. pylori should be offered eradication therapy.

D - Retesting after eradication should not be offered routinely, although the information it provides may be valued by individual patients.

A - If H. pylori has been excluded or treated and symptoms persist, offer either a low dose PPI or an H_2RA for one month.

D - If symptoms continue or recur following initial treatment, offer a PPI or H_2RA to be taken at the lowest dose possible to control symptoms, with a limited number of repeat prescriptions.

B - Discuss using PPI treatment on an "on-demand" basis with patients to manage their own symptoms.

A - Long-term, frequent dose continuous prescription of antacid therapy is inappropriate and only relieves symptoms in the short term rather than preventing them.

Helicobacter pylori: Testing and Eradication

C - H. pylori can be initially detected using either carbon-13 urea breath test or a stool antigen test, or laboratory-based serology where its performance has been locally validated.

D - Retesting for H. pylori should be performed using a carbon-13 urea breath test. (There is currently insufficient evidence to recommend the stool antigen test as a test of eradication.)

C - Office-based serological tests for H. pylori cannot be recommended because of their inadequate performance.

A - For patients who test positive, provide a seven day, twice daily course of treatment consisting of a full-dose PPI, with either metronidazole 400 mg and clarithromycin 250 mg or amoxicillin 1 g and clarithromycin 500 mg.

C - For patients requiring a second course of eradication therapy, a regimen should be chosen that does not include antibiotics given previously (see the British National Formulary for guidance).

Definitions:

Grading of Recommendation

Grade A: Based on hierarchy I evidence

Grade B: Based on hierarchy II evidence or extrapolated from hierarchy I evidence

Grade C: Based on hierarchy III evidence or extrapolated from hierarchy I or II evidence

Grade D: Directly based on hierarchy IV evidence or extrapolated from hierarchy I, II, or III evidence

Evidence Grade

Ia: Evidence from a meta-analysis of randomised controlled trials

Ib: Evidence from at least one randomised controlled trial

IIa: Evidence from at least one controlled study without randomisation

IIb: Evidence from at least one other type of quasi-experimental study

III: Evidence from observational studies

IV: Evidence from expert committee reports or experts

CLINICAL ALGORITHM(S)

Algorithms are provided in the original guideline document for the following:

- Guiding pharmacist management of dyspepsia
- Referral criteria and subsequent management
- Management of uninvestigated dyspepsia
- Management of gastro-oesophageal reflux disease
- Management of gastric ulcer
- Management of duodenal ulcer

- Management of non-ulcer dyspepsia

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence is specifically stated for each recommendation (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

This guideline is intended to:

- Guide healthcare professionals, patients and carers in the appropriate primary care management of dyspepsia.
- Promote the dialogue between professionals and patients on the relative benefits, risks, harms and costs of treatments.
- To identify effective and cost effective approaches to managing the care of adult patients with dyspepsia including diagnosis, referral and pharmacological and non-pharmacological.

POTENTIAL HARMS

- Antacids with magnesium may be laxative in some patients while those with aluminium may cause constipation.
- Historically oesophageal resection has been associated with one of the highest post-operative mortality of any of the routine surgical procedures
- There is a small (0.1 to 0.5%) but important post-operative mortality associated with anti-reflux surgery.
- There is some concern about the renal and cardiovascular safety of cyclooxygenase (COX-2) selective non-steroidal anti-inflammatory drugs (NSAIDs).

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The guideline development group assumes that healthcare professionals will use general medical knowledge and clinical judgement in applying the general principles and specific recommendations of this document to the management of individual patients. Recommendations may not be appropriate for use in all circumstances. Decisions to adopt any particular recommendation must be made by the practitioner in the light of circumstances presented by individual patients and available resources. Recommendations about drug treatment assume that clinicians will take account both of the response of individual patients and of the indications, contra-indications and cautions listed in the British National Formulary (BNF) or Summary of Product Characteristics. Clinicians will need to share appropriately the information within this guideline

to enable patients to participate in the process of decision making to the extent they are able and willing.
- This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Health professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not, however, override the individual responsibility of health professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Local health communities should review their existing practice for the management of people with dyspepsia against this guideline. The review should consider the resources required to implement the recommendations set out in the original guideline document, the people and processes involved, and the timeline over which full implementation is envisaged. It is in the interests of patients that the implementation timeline is as rapid as possible. Relevant local clinical guidelines, care pathways, and protocols should be reviewed in the light of this guidance and revised accordingly.

Suggested audit criteria are listed in Appendix D in the National Institute for Health and Clinical Excellence (NICE) version of the original guideline document. These can be used as the basis for local clinical audit, at the discretion of those in practice.

The following have been identified as priorities for implementation.

Referral for Endoscopy

- Review medications for possible causes of dyspepsia (for example, calcium antagonists, nitrates, theophyllines, bisphosphonates, corticosteroids and non-steroidal anti-inflammatory drugs [NSAIDs]). In patients requiring referral, suspend NSAID use.
- Urgent specialist referral for endoscopic investigation is indicated for patients of any age with dyspepsia when presenting with any of the following: chronic gastrointestinal bleeding, progressive unintentional weight loss, progressive difficulty swallowing, persistent vomiting, iron deficiency anaemia, epigastric mass, or suspicious barium meal.
- Routine endoscopic investigation of patients of any age, presenting with dyspepsia and without alarm signs, is not necessary. However, for patients over 55, consider endoscopy when symptoms persist despite Helicobacter pylori testing and acid suppression therapy, and when patients have one or more of the following: previous gastric ulcer or surgery, continuing need for NSAID treatment, or raised risk of gastric cancer or anxiety about cancer.

Interventions for Uninvestigated Dyspepsia

- Initial therapeutic strategies for dyspepsia are empirical treatment with a proton pump inhibitor (PPI) or testing for and treating H. pylori. There is currently insufficient evidence to guide which should be offered first. A 2-week washout period following PPI use is necessary before testing for H. pylori with a breath test or a stool antigen test.

Interventions for Gastro-oesophageal Reflux Disease (GORD)

- Offer patients who have GORD a full-dose PPI for 1 or 2 months.
- If symptoms recur following initial treatment, offer a PPI at the lowest dose possible to control symptoms, with a limited number of repeat prescriptions.

Interventions for Peptic Ulcer Disease

- Offer H. pylori eradication therapy to H. pylori-positive patients who have peptic ulcer disease.
- For patients using NSAIDs with diagnosed peptic ulcer, stop the use of NSAIDs where possible. Offer full-dose PPI or H_2 receptor antagonist (H_2RA) therapy for 2 months to these patients and, if H. pylori is present, subsequently offer eradication therapy.

Interventions for Non-ulcer Dyspepsia

- Management of endoscopically determined non-ulcer dyspepsia involves initial treatment for H. pylori if present, followed by symptomatic management and periodic monitoring.
- Re-testing after eradication should not be offered routinely, although the information it provides may be valued by individual patients.

Reviewing Patient Care

- Offer patients requiring long-term management of dyspepsia symptoms an annual review of their condition, encouraging them to try stepping down or stopping treatment.
- A return to self-treatment with antacid and/or alginate therapy (either prescribed or purchased over-the-counter and taken as required) may be appropriate.

H. pylori Testing and Eradication

- H. pylori can be initially detected using either a carbon-13 urea breath test or a stool antigen test, or laboratory-based serology where its performance has been locally validated.
- Office-based serological tests for H. pylori cannot be recommended because of their inadequate performance.
- For patients who test positive, provide a 7-day, twice-daily course of treatment consisting of a full-dose PPI with either metronidazole 400 mg and clarithromycin 250 mg or amoxicillin 1 g and clarithromycin 500 mg.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Clinical Algorithm
Patient Resources
Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

North of England Dyspepsia Guideline Development Group. Dyspepsia: managing dyspepsia in adults in primary care. Newcastle upon Tyne (UK): Centre for Health Services Research, University of Newcastle; 2004 Aug. 228 p. [466 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Aug

GUIDELINE DEVELOPER(S)

Newcastle Guideline Development and Research Unit - International Agency

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National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

North of England Dyspepsia Guideline Development Group

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Mr Mohammed Naseem (Joe) Asghar, Regional Pharmaceutical Advisor, University of Newcastle upon Tyne; Dr James Dalrymple, General Practitioner, Norwich; Dr Brendan Delaney, Technical Lead and General Practitioner, University of Birmingham; Dr Keith MacDermott, General Practitioner, York; Professor James Mason, Methodologist and Technical Support, University of Newcastle upon Tyne; Professor Paul Moayyedi, Consultant Physician and Technical Support, University of Birmingham and City Hospitals NHS Trust; Dr Anan Raghunath, General Practitioner, Hull; Mrs Mary Sanderson, Patient Representative, Harrogate; Dr Malcolm Thomas (Group Leader), General Practitioner, Northumberland, Dr Robert Walt, Consultant Physician, Birmingham Heartlands Hospital; Dr Stephen Wright, Consultant in Primary Care Medicine, Rotherham Primary Care Trust

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The following people have declared no competing interests in relation to the guideline:

Keith MacDermott; Mary Sanderson; Malcolm Thomas; Stephen Wright.

MN (Joe) Asghar is employed by the Department of Health and has previously worked for 3M Pharmaceuticals as a member of their professional advisory committee.

James Dalrymple is a member of the Primary Care Society of Gastroenterology, attending the annual meeting supported by Wyeth; he was a member of the Norfolk Dyspepsia Guidelines Group 1999 & 2001.

Brendan Delaney has received speaking honoraria from AstraZeneca UK, Astra-Zeneca Canada, Astra-Zeneca Sweden, AxCanPharma Canada, Eisai, but has never held a consultancy role; he has also received research grants in dyspepsia from the Medical Research Council and is supported by an NHS R&D Primary Care Career Scientist Award.

James Mason has previously received academic grants, fees and expenses for research and consultancy work from the UK Department of Health, medical charities and from the pharmaceutical industry who manufacture treatments discussed in this report.

Paul Moayyedi has received funding from the Medical Research Council; is a member of Gastroduodenal section of the British Society of Gastroenterology; is acting coordinating editor for the Cochrane upper gastrointestinal and pancreatic diseases group; is an Independent Medical Advisor for Astra-Zeneca and has received speakers' fees from AstraZeneca, Wyeth, Byk Gulden, Esai and Abbott.

Anan Raghunath has attended occasional Primary Care Advisory meetings with AstraZeneca; he is also studying for a PhD on Use of Proton Pump Inhibitors in General Practice at the University of Durham.

Robert Walt produced the first and revised BSG Dyspepsia Guidelines; has received academic support for education and research from GlaxoSmithKline, Astra, Janssen, Wyeth, Searle, MSD; and has no formal consultancy at present or in the past 5 years.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. 11 Strand, London, WC2N 5HR.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Newcastle Guideline Development and Research Unit. Dyspepsia. Management of dyspepsia in adults in primary care. NICE guideline. London (UK): National Institute for Health and Clinical Excellence (NICE); 2004 Aug. 45 p. (Clinical guideline; no. 17). Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.
- Dyspepsia - management of dyspepsia in adults in primary care. Quick reference guide. London: National Institute for Health and Clinical Excellence. 2004 Aug. 13 p. Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N0732. 11 Strand, London, WC2N 5HR.

Additionally, Audit Criteria can be found in Appendix D of the NICE version of the guideline document.

PATIENT RESOURCES

The following is available:

- Indigestion (dyspepsia) in adults: understanding NICE guidance - information for people with dyspepsia, their families and carers, and the public. London: National Institute for Health and Clinical Excellence. 2004 Aug. 30 p. Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N0690. 11 Strand, London, WC2N 5HR.

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NGC STATUS

This NGC summary was completed by ECRI on January 24, 2005. This summary was updated by ECRI on June 16, 2005, following the U.S. Food and Drug Administration advisory on COX-2 selective and non-selective non-steroidal anti-inflammatory drugs (NSAIDs).

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